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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------------|------------------|
| 10/034,075   | 01/03/2002  | Tomoharu Kajiyama    | HIRA.0021                   | 2462             |
| 7590 10/24/2003  |             |                      |                             |                  |
| REED SMITH LLP<br>Suite 1400<br>3110 Fairview Park Drive<br>Falls Church, VA 22042 |             |                      | EXAMINER<br>FORMAN, BETTY J |                  |
|  |             |                      | ART UNIT                    | PAPER NUMBER     |
|  |             |                      | 1634                        |                  |

DATE MAILED: 10/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/034,075             | KAJIYAMA ET AL.     |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | BJ Forman              | 1634                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8/03 1/0</u> . | 6) <input type="checkbox"/> Other: _____.                                   |

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## **FINAL ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 25 July 2003 in which claims 1 and 4 were amended. All of the amendments have been thoroughly reviewed and entered. The previous objections and rejections in the Office Action dated 23 April 2003, not reiterated below, are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 1-4 are under prosecution.

### ***Specification***

2. The amendment filed 25 July 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Claim 1 has been amended to recited "islands are spaced from each other with intervals filled with a heat insulating material". Applicant points to page 6, line 15 for support for the newly added limitation. Page 6, line 15 recites:

"The islands are spaced from each other. The spaces among the islands serve as a substitute for heat insulating material, and so the temperature of each island can easily be controlled independently."

This recitation does not teach intervals filled with a heat insulating material as newly claimed. In contrast, this recitation teaches that heat insulating material is not present and

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not required because spaces substitute for any heat insulating material. As such, the amendment to Claim 1 introduces new matter into the disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation "filled with a heat insulating material" is added to the newly amended Claim 1, from which Claims 2-4 depend. However, the specification fails to define or provide any disclosure to support such claim recitation.

Applicant points to page 6, line 15 for support for the newly added limitation. Page 6, line 15 recites:

"The islands are spaced from each other. The spaces among the islands serve as a substitute for heat insulating material, and so the temperature of each island can easily be controlled independently."

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This recitation does not teach intervals filled with a heat insulating material as newly claimed. In contrast, this recitation teaches that heat insulating material is not present and not required because spaces substitute for any heat insulating material. As such, the amendment to Claim 1 contains subject matter which was not described in the originally filed specification.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application

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designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Yasuda et al (U.S. Patent No. 6,093,370, filed 10 June 1999) as defined by Giancoli, D.C. (Physics: Principles with Applications, 3<sup>rd</sup>., Prentice Hall, NJ, 1991, pages 379-382).

Regarding Claim 1, Yasuda et al disclose a biochemical reaction detection apparatus comprising a first membrane, a plurality of island on one side of the membrane and probe cells for immobilizing probes said probe cells being provided on an opposite side of the membrane wherein the islands are spaced from each other with intervals filled with a material (Fig. 11) and each of the islands is provided with a temperature controller for heating and temperature control of the probe cells (Column 11, lines 43-62) wherein the heating and temperature of the probe cells are controlled independently (Column 11, lines 54-62 and Column 13, lines 5-24). Yasuda et al further teach that the space between the islands is filled with an insulating material (Column 11, lines 43-62). While they do not specifically teach the material is heat insulating, it was well known in the art that insulation and conduction are inversely related relative properties i.e. poor conductors are good insulators and good conductors are poor insulators (Giancoli, page 380, last paragraph-page 381). Therefore, all materials have heat insulating properties as defined by Giancoli. Hence, the material between the islands of Yasuda is heat insulating.

7. Claim 4 is rejected under 35 U.S.C. 102(e) as being anticipated by Yasuda et al (U.S. Patent No. 6,093,370, filed 10 June 1999) as defined by Giancoli, D.C. (Physics: Principles with Applications, 3<sup>rd</sup>., Prentice Hall, NJ, 1991, pages 379-382) and Handbook of Chemistry and Physics, The Chemical Rubber Publishing Co., Cleveland, Ohio, 1963, pages 2527-2531).

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Regarding Claim 4, Yasuda et al disclose a biochemical reaction detection apparatus comprising a first membrane, a plurality of island on one side of the membrane and probe cells for immobilizing probes said probe cells being provided on the other (opposite) side of the membrane wherein the islands are spaced from each other with intervals and each of the islands is provided with a temperature controller for heating and temperature control of the probe cells (Column 11, lines 43-62) wherein the membrane is thermally insulating (Column 11, lines 44-46) e.g. glass (Column 13, lines 35-57).

Yasuda et al further teach that the space between the islands is filled with an insulating material (Column 11, lines 43-62). While they do not specifically teach the material is heat insulating, it was well known in the art that insulation and conduction are inversely related relative properties i.e. poor conductors are good insulators and good conductors are poor insulators (Giancoli, page 380, last paragraph-page 381). Therefore, all materials have heat insulating properties as defined by Giancoli. Hence, the material between the islands of Yasuda is heat insulating.

Furthermore, the Handbook of Chemistry and Physics provides the thermal conductivity of glass as being between 0.001-0.0025 calories/second · centimeter (depending on the type of glass). Converting calories/second · centimeter to w/mk (1 calorie/second · centimeter =418.5 w/mk) the glass substrate of Yasuda et al has a conductivity of between 1.0 and 0.4 w/mk which is less than 10w/mk as instantly claimed.

### **Response to Arguments**

8. Applicant argues that in contrast to the instant invention, the intervals of Yasuda are filled with heat conductive (not insulating) material. The argument has been considered but is not found persuasive because, as discussed above, conduction and insulation are properties of all materials i.e. materials have conducting and insulating abilities. While some materials are good insulators and poor conductors, they still have conducting and insulting properties



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(see Giancoli as discussed above). Therefore, the material of Yasuda is an insulating material as defined by Giancoli. Furthermore, Yasuda et al teach that the probe areas are temperature and heat controlled individually as claimed (Column 11, lines 54-62 and Column 13, lines 5-24).

Applicant further argues that the glass substrate of Yasuda's embodiment III is not equal to the substrate of Yasuda's embodiment II. The argument has been considered but is not found persuasive because Yasuda consistently defines their substrate as "substrate 1" (e.g. Column 4, lines 54-57; Column 5, lines 5-10; Column 11, lines 44-47; and Column 13, lines 35-38). Yasuda defines the composition of "substrate 1" as glass (Column 13, lines 35-38). As such, Yasuda defines "substrate 1" as glass.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yasuda et al (U.S. Patent No. 6,093,370, filed 10 June 1999) as defined by Giancoli, D.C. (Physics: Principles with Applications, 3<sup>rd</sup>., Prentice Hall, NJ, 1991, pages 379-382) in view of Sosnowski et al (U.S. Patent No. 6,051,380, filed 5 December 1997).

Regarding Claims 2 and 3, Yasuda et al disclose a biochemical reaction detection apparatus comprising a first membrane, a plurality of island on one side of the membrane and



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probe cells for immobilizing probes said probe cells being provided on an opposite side of the membrane wherein the islands are spaced from each other with intervals filled with heat insulating material (as defined by Giancoli and discussed above) and each of the islands is provided with a temperature controller for heating and temperature control of the probe cells (Column 11, lines 43-62) but they are silent regarding the length of intervals between the islands. However, intervals of longer than 50 $\mu$  m (Claim 2) and longer than 100 $\mu$  m (Claim 3) were well known in the art at the time the claimed invention was made as taught by Sosnowski et al (Column 23, lines 16-23 and 52-54). Sosnowski et al teach a similar biochemical detection apparatus comprising a first membrane, a plurality of island on one side of the membrane and probe cells for immobilizing probes said probe cells being provided on the other (opposite) side of the membrane wherein the islands are spaced from each other with intervals (Column 21, lines 36-Column 22, line 30) wherein due to the complexity of underlying circuitry, the interval (spacing) between islands is determined based on the number of islands i.e. as the number of islands increase, the spacing increases proportionally (Column 23, lines 16-23) wherein a support having 64 microlocations has intervals of 50 $\mu$  m (Column 23, lines 46-54). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the island intervals of Sosnowski et al to the apparatus of Yasuda et al and to design their apparatus to have intervals of 100 $\mu$  m or longer based on the teaching of Sosnowski et al wherein the as the number of islands increase, the spacing increases proportionally (Column 23, lines 16-23). Therefore, one of ordinary skill in the art would have been motivated to provide intervals of 100 $\mu$  m or longer based on a desired number of island being greater than 128 as suggested by the teaching of Sosnowski et al wherein 50 $\mu$  m intervals are required for 64 islands and intervals increase proportionally with the number of islands based on the complexity of required circuitry (Sosnowski et al, Column 23, lines 16-23 and 52-54).

**R sponds to Arguments**

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11. Applicant argues that Sosnowski fails to cure the deficiencies of Yasuda. The argument has been considered but is not found persuasive because, as stated above, Yasuda meets teaches the limitations of Claim 1.

### ***Double Patenting***

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,428,749. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a biochemical reaction detection chip and differ only in the limitations of instant Claims 2 and 3 and in the arrangement of the limitations e.g. independent Claim 1 of the '749 patent recites the substrate has a heat conductivity of 10w/mk or less while instant Claim 4 which depends from Claim 1 recites this conductivity limitation. Instant Claims 2 and 3 are drawn to the length of the intervals between the islands. While the '749 claims do not recite these interval limitations, the disclosure of the specification defines their claimed islands as having intervals equal to those instantly claimed (Column 3, lines 30-31). As such, the instantly claimed detection chip is obvious in view of the '749 detection chip, as defined by the patent disclosure (Column 3, lines 30-31).

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### **Response to Arguments**

14. Applicant argues that the instant claims differ from the patent claims because the instant claims, as amended, are drawn to “intervals filled with heat insulating material”. The argument has been considered. However, because the amendment introduces new matter, not described in the originally filed specification, the above rejection is maintained.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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**Conclusion**

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
October 21, 2003